IFW

Docket No.: 0020-5041PUS2
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Mitsutaka NAKAMURA et al.

Application No.: 10/525,021 | Confirmation No.: 3141

Filed: February 18, 2005 | Art Unit: N/A

For: AGENT FOR TREATMENT OF SCHIZOPHRENIA | Examiner: Not Yet Assigned

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Subsequent to the filing of the above-identified application on February 18, 2005, attached hereto is an English translation of the International Preliminary Examination Report (Form PCT/IPEA/409) that should be made of record in the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated:

SEP - 8 2005

Respectfully submitted,

By _____
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Attachment(s)

DRN/ETP/py

Translation

PCT/JP2003/010490

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 663962	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2003/010490	International filing date (*day/month/year*) 20 August 2003 (20.08.2003)	Priority date (*day/month/year*) 22 August 2002 (22.08.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/496, A61P 25/18 // C07D 417/12		
Applicant SUMITOMO PHARMACEUTICALS COMPANY, LIMITED		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

   ☒ Box No. I Basis of the report
   ☐ Box No. II Priority
   ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   ☐ Box No. IV Lack of unity of invention
   ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   ☐ Box No. VI Certain documents cited
   ☐ Box No. VII Certain defects in the international application
   ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
26 January 2004 (26.01.2004)	17 August 2004 (17.08.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2003/010490

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2003/010490

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-13

because:

☒ the said international application, or the said claims Nos. 1-13 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

See supplemental sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1-13 .

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ see Supplemental Box for further details.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III. 1

Claims 1-13 pertain to methods for treatment of the human body by surgery or therapy and to diagnostic methods, and thus relate to subject matter which does not require international preliminary examination by this International Preliminary Examining Authority.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP 03/10490

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	14-19	NO
Inventive step (IS)	Claims		YES
	Claims	14-19	NO
Industrial applicability (IA)	Claims	14-19	YES
	Claims		NO

2. Citations and explanations

Documents

1. EP 464846 A1 (Sumitomo Pharmaceuticals Co., Ltd.), 8 January 1992
2. WO 02/24166 A1 (Sumitomo Pharmaceuticals Co., Ltd.), 28 March 2002

Explanations

Claims 14-19

The inventions set forth in claims 14-19 are not novel and do not involve an inventive step in the light of document 2, cited in the international search report. Document 2, in examples, discloses oral preparations containing 10 mg, 20 mg or 40 mg of a hydrochloride of a compound represented by formula (1) in claim 14, which are efficacious for treating schizophrenia (an integration dysfunction syndrome) and the like.

The inventions set forth in claims 14-19 also do not involve an inventive step in the light of documents 1 and 2, cited in the international search report. Document 1 discloses the fact that compounds represented by formula

(1) in claim 14 or pharmaceutically permissible salts thereof are efficacious for treating schizophrenia (an integration dysfunction syndrome), and that in the case of oral administration they can be administered at 1-1000 mg, and preferably 5-100 mg, daily in a single dose or in several divided doses. Therefore, a person skilled in the art could easily conceive of selecting a suitable oral dose and number of treatments daily, considering factors such as the drug being used and adverse reactions, as a measure of the content of the active ingredient in an oral preparation disclosed in document 2.